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(4) Device for receiving cartridges and cartridges therefor.

(9) Device for receiving cartridges (12) and cartridges (12) therefor. The device includes adjustable discriminator means (14) for cooperation with codes (16) on the cartridges (12). The code (16) on each cartridge (12) is indicative of the type of test slides contained by the cartridge (12). The discriminator means (14) is adjusted so that it allows only a cartridge (12) containing a perticular chosen type of test slide to be received by the device. The device is included in a chemical analyzer for body fluids.

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# DEVICE FOR RECEIVING CARTRIDGES AND CARTRIDGES THEREFOR

This invention relates to a device for receiving cartridges containing test elements, and to such cartridges.

Chemical analyzers have been developed for performing quantitative analyses of samples of biological fluids, such as blood serum, to enable the physician to obtain a more complete picture of a 10 person's physical condition. Recent developments have provided test elements in essentially planar, dry form which can be loaded into a cartridge adapted to be removably mounted in an analyzer. In the use of the analyzer, a test element is fed from a cartridge into a metering station where a predetermined amount of sample fluid is deposited on the test element. The 15 element is then moved to a read station where a change in the test element is sensed, the amount of change being proportional to the concentration of a particular 20 analyte in the sample fluid. The test element is used only once and is discarded after the reading has been taken. An analyzer for use with test elements of this type is described in U.S. Patent No. 4151931.

Cartridges of th typ described above are normally loaded with test 1 ments f r performing a

single test, for example an analysis of the concentration of sodium ions in blood serum. The cartridges must be generally uniform in size and shape, regardless of the type of test element which they contain, since each of the cartridges must fit into cartridge support structure of fixed dimensions. Thus, there is a problem that a cartridge containing the wrong type of element for the test desired may be inserted in the analyzer, particularly in a busy laboratory where many samples are analyzed daily. This, of course, results in erroneous test results and in a loss of valuable time when the analyses must be performed under emergency conditions.

It is an object of one aspect of the present

invention to overcome the above-mentioned problem in a
device for receiving a cartridge containing test
elements of one of a plurality of types, the device
including means for receiving a cartridge and being
intended to operate with a cartridge having a code
indicative of the type of the elements it contains.

According to this one aspect of the invention such a device is characterized by adjustable discriminator means for cooperation with the code of the cartridge to allow or prevent receipt of a cartridge according to the form of the code and the condition of the discriminator means. The condition of the discriminator means is adjustable so that the type of the elements in a cartridge which is received can be governed.

In furtherance of the object of overcoming the above-mentioned problem, another aspect of the present invention provides a cartridge containing test elements and receivable in a device for employing the test elements. The device has adjustable discriminator means for cooperation with a tactile code on the cartridge to allow or prevent receipt of a cartridge in the devic. The cartridge is characterized in that

the tactile code is indicative of the type of test elements in the cartridge and that the tactile code is one of a plurality of tactile codes present one on each of a range of similar cartridges and each being indicative of the type of test elements present in the cartridge of which it is part.

A further aspect of the present invention provides a cartridge containing test elements of one of a plurality of types in combination with a device for employing said test elements, characterized in that the device has adjustable discriminator means which is adjustable to cooperate with a code on the cartridge to allow receipt of the cartridge in the device, the code being one of a plurality of codes present one on each of a range of similar cartridges each code being indicative of the type of test elements present in the cartridge of which it is part.

Embodiments of the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Fig. 1 is a perspective view of a reagent supply station of a chemical analyzer, showing a cartridge support means and a cartridge discriminator, including a first form of sensing wheel, constructed in accordance with a preferred embodiment of the invention;

Fig. 2 is a perspective view showing a cartridge positioned for insertion into the cartridge chamber of an analyzer;

Fig. 2a is a diagrammatic fragmentary plan view of the chamber into which the cartridge is to be inserted;

Fig. 3 is an exploded view of a cartridge, showing the cartridge casing, a test element stack, and a stack positioning element;

Fig. 4 is a perspectiv view of another form of sensing wheel included in a second mbodiment of th invention;

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Fig. 5 is an elevational view, partially in section, of the cartridge support means in combination with the sensing wheel shown in Fig. 4;

Fig. 6 is a partial view with parts broken away for the sake of illustration, of a third embodiment of the present invention; and

Fig. 7 is a sectional view taken generally on the line VII-VII in Fig. 6 when the cartridge is in its nest.

The invention is described hereinafter in connection with an analyzer for performing quantitative chemical analyses of biological fluids, such as blood serum.

The invention is particularly useful with potentiometric analyzers in which case the substrate which makes the test possible comprises a pair of electrodes selective to the ion activity of choice. Recent developments have provided these electrodes in essentially planar, dry form, suitable for use in pairs in an analyzer. The invention can also be employed in an analyzer using a radiometric detector which will read a suitable substrate incorporating, for example, reagents that create a dye in proportion to concentration of the analyte being measured.

In accordance with a preferred embodiment of the invention, there is shown in Fig. 1 a test element supply station of an analyzer which includes a cartridge support means 10. Support means 10 comprises walls 13 which define a chamber 11 for receiving a cartridge 12 containing test elements for use in the analyzer. As will be described in more detail hereinafter, a cartridge discriminator 14 is adapted to interact with a code means 16 on cartridge 12 to ensure that only a cartridge containing th proper test elem nts is install d on the analyzer.

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As shown in the exploded view in Fig. 3, the cartridge 12 is generally rectangular in cross section and is formed from a pair of casing sections 18 and 20 which are permanently sealed together to enclose a 5 stack of test elements 22 each of which contains the reagents necessary for performing a selected test. Test elements 22 are adapted to be sequentially fed from cartridge 12 by a transfer means having a push blade 24, shown in phantom in Fig. 3, which enters 10 through a slot 26 and forces a test element 22 in a dispensing position out of the cartridge 12 through an exit slot (not shown). A stack-positioning element 28 bears against the lowermost test element 22 in the stack and is biased upwardly by a spring loaded plunger 30, 15 shown in phantom in Fig. 3, which extends into the cartridge 12 through an aperture 31 in its bottom wall. Stack positioning element 28 comprises a pair of pawls 32 on opposite sides thereof which are adapted to engage ratchet teeth 34 to prevent movement of the test 20 elements 22 downwardly away from the dispensing position.

To ensure proper orientation of cartridge 12 in chamber 11, cartridge casing section 18 is provided with a pair of vertical rails 36, 38; and casing section 20 is provided with vertical rails 39, 40 which are spaced more closely than rails 36, 38.

As shown in Fig. 2A, chamber ll is provided with channels 42 and 44, the channel 44 being narrower than channel 42 so that it can accept only the more closely spaced rails 39, 40, and not the more widely spaced rails 36, 38. This arrangement in addition to the non-square, rectangular sectional shape of the cartridge 12 prevents insertion of the cartridge 12 in the chamber 11 in any ori ntation other than that required. The rails 36, 38, 39, 40 cooperating with walls 36a, 38a, 39a, 40a, resp ctiv ly, also

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serve to accurately control the position of the cartridge 12 during insertion and while in the chamber 11.

Cartridge 12 is secured in the chamber 11 by means of a hinged cover member (not shown).

The type of test element 22 contained in cartridge 12 is indicated by code means 16 on the cartridge 12. Code means 16 comprises a web 49 having tactile discontinuities thereon in the form of a notch, as shown at 47. Each of the types of test elements is assigned a unique notch code, the different codes being formed by varying the location of the notch 47. Although the code means 16 is shown as having only one notch 47 in respect of each notch code a plurality of notches 47 could in fact be used in respect of each

Test elements 22 suitable for use in the device and cartridge of the subject invention are disclosed in U.S. Patents Nos. 4,053,381 and 3,992,158.

15 notch code.

Cartridge discriminator 14 (Fig. 1) is

- 20 provided to ensure that only a cartridge 12 containing test elements 22 for a selected analyte can be installed on the analyzer. Cartridge discriminator 14 comprises a sensing wheel 50 which includes a central hub 51 and projections 66 extending radially from the hub.
- 25 Sensing wheel 50 is carried on a shaft 52 journalled in supports 54, 56, in the analyzer.

Sensing wheel 50 is adjustable to five angular positions by a control means which includes a control knob 58 mounted on shaft 52. The projections 30 66 are circumferentially and axially positioned on hub 51 such that, in each of the angular positions of wheel 50, a different combination, or pattern, of projections 66 extends into chamber 11 and is in a position to interact with code means 16 on cartridge 35 12.

Thus, as shown in Fig. 1, a projection 66 at one axial end 53 of central hub 51 is positioned such that only a cartridge 12 having a notch 47 in the position shown could be installed in chamber 11. Control knob 5 58 has a plurality of faces 59, only one of which is visible to the operator at any one time. The face 59 which is in the visible, or "up," position in Fig. 1 is marked with the symbol "K" for potassium, indicating that the apparatus is programmed for a potassium test as will be explained hereinafter, and that sensing wheel 50 is positioned to permit insertion of a cartridge 12 having a code means 16 corresponding to potassium test elements. In a like manner, when the face 59, labelled "Na" for sodium, is moved to the "up" 15 position, the apparatus will be conditioned for a sodium analysis. A detent 60 is provided to position knob 58 and to precisely locate wheel 50 relative to the chamber 11 in each of its angular positions; detent 60 comprises a leaf spring 20 63 having an indentation 65 which is adapted to releasably receive protuberances 67 on the control knob 58. A ratchet wheel 62 cooperates with a pawl 64 to provide an anti-backup device for control knob 58; thus, as shown in Fig. 1, knob 58 can only be rotated 25 in a counterclockwise direction.

Ratchet wheel 62 and pawl 64 also function to prevent rotation of shaft 52 when an attempt is made to insert a cartridge 12 containing the wrong type of test elements 22 into chamber 11. With reference to Fig. 1, it will be seen that a torque on shaft 52 in a clockwise direction is created when a web 49 is moved down into abutment with a projection 66; clockwise movement of shaft 52 is prevented by ratchet wheel 62 and pawl 64, and henc, further insertion of cartridg 35 12 is not possible.

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A detector 70 is provided to sense the position of shaft 52, the shaft position being indicative of the particular test selected by the operator, and to transmit the test selection to the analyzer computer (not shown). Detector 70 could take the form of an encoder wheel and a photoelectric detector, or it could be a set of switches which are coupled to logic circuitry. Information stored in the computer for the particular test selected will be utilized in processing the data produced by the test.

By having the cartridge discriminator 14 located adjacent the mouth of the chamber 11 and by having the code means 16 located adjacent the leading end of the cartridge 12, prevention of insertion of a wrong type of cartridge 12 will occur very early in the movement of the cartridge 12 into the chamber 11. Hence it will be blatantly apparent that there is an error.

The cooperation of the rails 36, 38, 39, 40
20 with the walls 36a, 38a, 39a, 40a, serves to ensure that the position of the cartridge 12 and hence of a notch 47 in the web 49, is accurately determined as the web 49 approaches the cartridge discriminator 14 upon an attempt being made to insert the cartridge 12.

A second embodiment of the invention is, in all respects except that of the form of the sensing wheel, identical to the first embodiment described above. Accordingly only the sensing wheel will be described below. For an understanding of other aspects of the second embodiment reference should be made to the description and illustrations of the first embodiment.

In the second embodiment a sensing wheel 150, illustrated in Figs. 4 and 5, is included instead of the sensing wheel 50. Sensing wheel 150 mounted on shaft 52, is of generally polygonal cross-sectional form

and comprises a plurality of generally planar surfaces
151 having projections 166 formed thereon. Each projection 166 is adapted to cooperate with a notch 47
in the web 49 of a cartridge 12 in the same manner as
described previously for projections 66. Wheel 150
can be moulded, or projections 166 can be formed by a
machine operation. One particular advantage in the
use of sensing wheel 150 is that the wheel 150 cannot be
rotated when a cartridge 12 is installed in chamber 11,
because of the length of the projections 166. (See
Fig. 5.) Thus, the control knob 58 setting cannot be
accidentally changed when a cartridge 12 is installed in
the analyzer.

In operation of the first and second

15 embodiments, control knob 58 is first moved to
position a face 59 bearing the notation for the
desired test, in the "up" position, e.g. for potassium
as shown in Fig. 1. Next, a cartridge 12 containing
test elements 22 for performing the desired test is

20 inserted in chamber 11. If the proper cartridge 12 is
selected, the code means 16 on the cartridge 12 will be
located such that the projection(s) 66 (or 166) on
the sensing wheel 50 (or 150) will pass through the
notch(es) 47, and the cartridge 12 will move into the

25 position shown in Fig. 1. If the wrong cartridge 12 is
selected, web 49 will abut against the projections 66 or 166
and the cartridge 12 will not move to the loaded position.

It will be apparent from the foregoing description that embodiments of the invention are particularly suitable for ensuring that only test elements appropriate for a desired test are installed on the analyzer and that the analyzer is properly programmed for the selected tests. Thus, costly mistakes, resulting from loading th analyzer with reag nts which do not conform to a desired t st, can

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be avoided. A single-channel analyzer can be conditioned to accept cartridges bearing a number of different notch codes. Further, a plurality of identical channels, each having a cartridge discriminator 14 5 can be combined to form a multi-channel analyzer capable of simultaneously performing different tests. Use of the same components in each channel greatly facilitates the manufacture and repair of such a multi-channel analyzer.

A third embodiment of the present invention is illustrated in Figs. 6 and 7. This third embodiment is intended for cooperation with a cartridge substantially the same as that already described herein, except that it has two webs 49. Therefore, 15 there will be no repetition of the description of the cartridge 12.

Only those features of the third embodiment which differ from the first and second embodiments will now be described. Features which are structurally 20 and/or functionally the same as features in the first and/or second embodiment will be given the same reference numeral but with the addition of a prime (') suffix. For an understanding of features not described in this third embodiment reference should be made to the foregoing description and Figs. 1 to 5 herein.

In this third embodiment the cartridge discriminator consists of pins 301 received in bores 303 in walls 13' of the cartridge support means 10'. 30 In the embodiment illustrated there are three bores 303a,b,c aligned with the three possible sites of notches 47 in the web 49a and there are three bores 303d,e,f, aligned with the three possible sites of notches 47 in the web 49b. The web 49a is disposed 35 betwe n the rails 36 and 38, and the w b  $49\underline{b}$  is dispos d betwe n the rails 39 and 40.

The pins 301 are long nough so that when inserted into bores 303 they extend from the inner surface of the walls 13' and into the path of an unnotched web 49' as the cartridge is inserted into its chamber 11'.

Thus, any one pin 301 will prevent full and proper insertion of a cartridge 12 into the chamber 11' unless a notch 47' is aligned with that pin 301.

Let it be assumed that the operator wishes to perform tests for potassium. He will set up the apparatus so that only test elements 22 appropriate for potassium tests can be supplied to the apparatus. Let it further be assumed that cartridges containing test elements for potassium tests have a notch 47 in the middle of web 49a and a notch 47' adjacent rail 39' (as is illustrated in Fig. 7). The operator will insert a pin 301 in bore 303b and a pin in bore 303d. The ends of such pins will not prevent insertion of a cartridge containing potassium test elements 22 because the notches 47' will allow the pin ends to 20 pass relatively through the webs 49a and 49b. However, any location of the notches 47' other than that shown will cause interference between a web or the webs and a pin or the pins and hence prevent full and proper 25 insertion of the cartridge 12'. The operator will notice that full insertion of the cartridge 12' is prevented and

will be caused to check the cartridge 12'.

In Fig. 7, the cartridge is illustrated without any test elements therein and with the stack
30 positioning element removed, for the sake of illustration.

In the first and second embodiments the cartridge discriminator 14 includes a single sensing wheel 50, 150 respectively for cooperation with code means 16, on 35 th cartridg 12, which in ludes a single web 49. It should be understood that apparatus therwise similar

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to the first and second embodiments may include two sensing wheels 50, 150 for cooperation one with each of two webs 49 arranged, perhaps, in the manner of the third embodiment.

As will be apparent from the above description, the third embodiment does not have some of the advantageous features of the first and second embodiments.

Further alternative arrangements of the present invention include the use of a bar code which is optically 10 read or a magnetically sensed code.

#### CLAIMS

- 1. A device for receiving a cartridge
  (12) containing test elements (22) of one of a
  plurality of types and having a code (16) indicative
  of the type of the elements, said device including
  means (11, 11') for receiving a cartridge, characterized by adjustable discriminator means (14, 301,
  303) for cooperation with the code (16) to allow or
  prevent receipt of a cartridge (12) according to the
  form of the code (16) and the condition of the
  discriminator means (14, 301, 303), the condition of
  the discriminator means (14) being adjustable so that
  the type of the elements (22) in a cartridge (12)
  which is received can be governed.
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  2. A device according to claim 1 wherein the code (16) on the cartridge (12) is tactile, characterized in that the adjustable discriminator means (14, 301, 303) is adapted to sense a tactile code (16).
- 3. A device according to claim 2, characterized in that the discriminator means includes elements (66, 166, 301) which can be selectively positioned to form a plurality of distinct element patterns, each of said element patterns being adapted to cooperate with a specific respective code on a cartridge (12).
- 4. A device according to claim 3, for receiving a cartridge in which the code includes a web (49) having a notch therein, characterized in that the discriminator means includes a sensing wheel (50, 150) mounted for rotation, and that the elements are radial projections (66, 166) on the sensing wheel (50;150).
- 5. A device according to claim 3, for receiving a cartridge in which the code includes a web having a notch therein, characterized in that the discriminator means includes at least one pin (301)

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mountable in a selected one of a plurality of positions (303), each of said positions being related to a respective one of the plurality of possible locations of a notch (47) in the web (49) of the 5 cartridge (12), a portion of the pin (301) being so disposed as to interfere with the web (49) when endeavours are made to insert a cartridge (12) containing test elements (22) of a type other than that appropriate to the positional setting of the pin (301).

- A device according to claim 4, char-6. acterized in that the sensing wheel (150) includes a portion having a polygonal sectional form and the elements are rib-like raised portions (166) of the polygonal sectional form portion.
- A device according to 7. claim 4 or 6, characterized by an anti-backup device (62, 64) for preventing rotation of the sensing wheel (50) under the influence of the cartridge (12) upon the cartridge being inserted.
- A device according to claim 4, 6 or 7, characterized by means (70, 59) associated with the discriminator means (14) for producing a signal indicative of the condition of the discriminator means.
- A device according to claim 4, 6, 7 or 9. 8, characterized in that the sensing wheel (50, 150) has a plurality of stable positions, the number of positions corresponding to the number of different tests, and in that said projections (66; 166) are disposed in a like number of positions circumferentially of the wheel and are disposed axially at each position to create a unique pattern.
- A device according to claim 9, char-10. acterized by a control knob (58) manually rotatable 35 to s t the sensing wh el (50, 150), the knob having indicia indicative of th types of test.

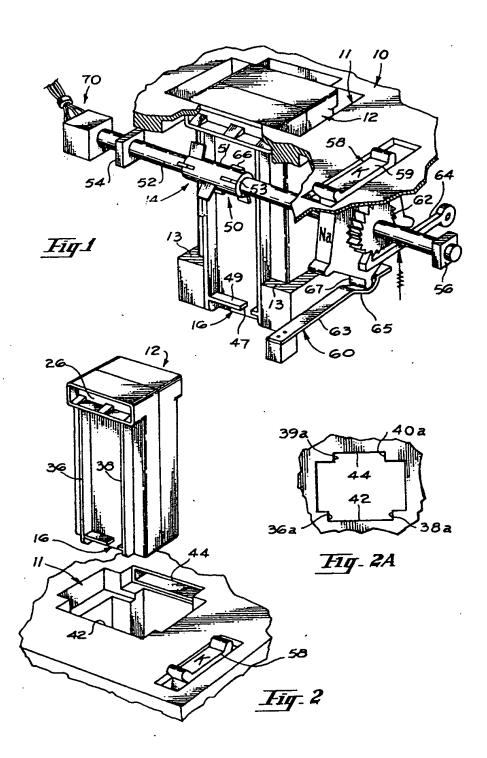
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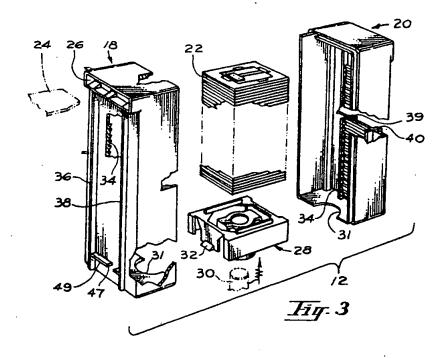
- 11. A device according to any one of the
  preceding claims, characterized in that means for
  receiving a cartridge includes a chamber (11, 11')
  having channels (42, 44; 42', 44') in opposite walls,
  and that the discriminator means (14, 301, 303)
  projects into at least one of said channels.
- and receivable in a device for employing said test elements, the device having adjustable discriminator means (14, 301, 303) for cooperation with a tactile code (16) on the cartridge (12) to allow or prevent receipt of the cartridge in the device, characterized by a tactile code (16) which is indicative of the type of test elements (22) in the cartridge (12), and in that the tactile code is one of a plurality of tactile codes present one on each of a range of similar cartridges and each being indicative of the type of test elements present in the cartridge of which it is part.
- 20 13. A cartridge according to claim 12, characterized in that the tactile code includes a web (49) having a notch (47).
- 14. A cartridge according to claim 12
  or 13, characterized in that the tactile code (16) is
  25 adjacent that end of the cartridge which leads upon insertion of the cartridge into the device.
- 15. A cartridge according to claim 12, characterized in that the tactile code includes a web (49) having a notch (47), and that the web extends 30 between a pair of rails (36, 38; 39, 40) extending parallel to the longitudinal axis of the cartridge.
- 16. A cartridge containing test elements of one of a plurality of types in combination with a device for employing said test elements, characterized in that
  35 the device has adjustable discriminator means (14;301, 303) which is adjustable to cooperat with a code (16) on the

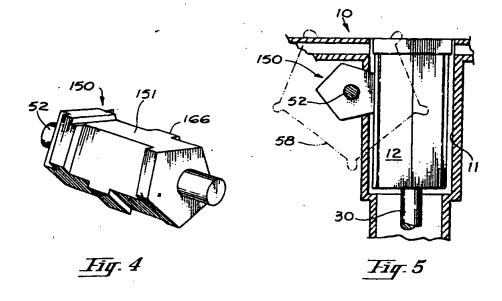
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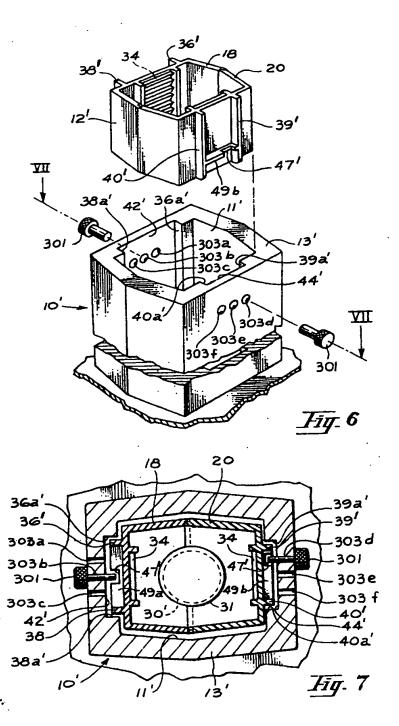
cartridge (12) to allow receipt of the cartridge (12) in the device, the code being one of a plurality of codes present one on each of a range of similar cartridges, each code being indicative of the type of test elements present in the cartridge of which it is part.



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### **EUROPEAN SEARCH REPORT**

Application number EP 79 30 1061

	DOCUMENTS CONSID	CLASSIFICATION OF THE APPLICATION (Int. Cl. <sup>2</sup> )		
Category	Citation of document with Indica passages	tion, where appropriate, of relevant	Relevar to clain	nt 1
A	FR - A - 2 236 18 LABORATORY AUTOMA		h	G 01 N 1/00 B 01 L 9/06
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	* Page 21, line 2 line 1; figure	0 to page 22, 2 *		
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	* Page 4, lines 2	0-26 *		G 01 N 1/00 33/16
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	* Page 7, line 4 9; figures 1,2	to page 8, line		
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A	FR - A - 2 350 59 DOUGLAS CORP.)	3 (McDONNELL	1	
	* Page 2, lines 1	8-32; figure 1 *		
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P	US - A - 4 142 86	3 (R.G. COVINGTON	1-3,5	X: particularly relevant A: technological background
	* Column 3, line	64 to column 4.		O: non-written disclosure P: intermediate document
	line 17; figures 4,5 *			T: theory or principle underlyi
	<del>-</del> -			the Invention  E: conflicting application
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